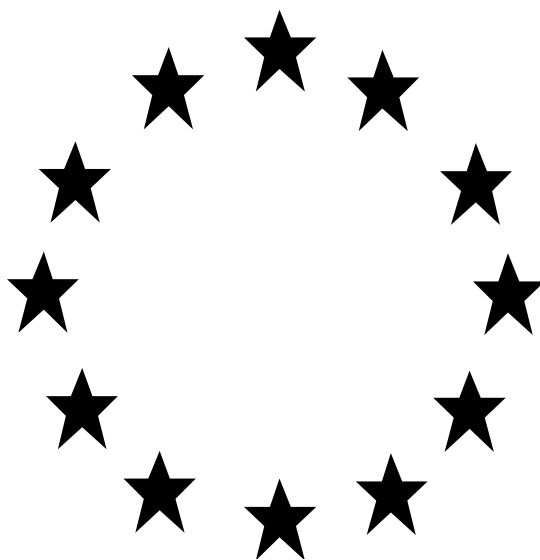




Draft Assessment Report (DAR)

- public version -

**Initial risk assessment provided by the rapporteur Member State
Portugal for the existing active substance**

CALCIUM CARBIDE

**of the fourth stage of the review programme
referred to in Article 8(2) of Council Directive 91/414/EEC**

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PORTUGAL

MINISTÉRIO DA AGRICULTURA DO DESENVOLVIMENTO RURAL E DAS PESCAS
DIRECÇÃO-GERAL DE AGRICULTURA E DESENVOLVIMENTO RURAL

**Report prepared in the context of the inclusion of Calcium carbide
in Annex I of the Council Directive 91/414/EEC**

CALCIUM CARBIDE

Volume 3

Annex B

**Summary, evaluation and assessments of the data.
List of tests and studies relied upon**

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WARNING: This document forms part of an Evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

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B.1 Identity

A dossier was submitted for the evaluation of the active substance calcium carbide.

For the proposed use (repellent), technical calcium carbide needs to contain calcium phosphide (0.02%w/w) for the production of phosphine in the presence of moisture. Phosphine has a garlic odour and in fact it is the repellent active substance.

Experts present in the PRAPeR 06 Meeting, organised by EFSA, agreed that RMS should evaluate and report the real active substance calcium phosphide. Due to the fact that phosphine is a very toxic gas, it was also agreed by those experts to set a range in the specification (minimum and maximum purity) of calcium phosphide, to prevent having a different function for this active substance, e.g. rodenticide, if the content of calcium phosphide present in calcium carbide would be much higher.

However, Commission decided that the DAR should be finalised for the calcium carbide as it was included in the 4th stage review programme and is authorised for use in that form.

Hereafter calcium carbide should be regarded as a technical with a very low content of calcium phosphide.

B.1.1 Identity of the active substance

B.1.1.1 Applicant (name, address, contact, telephone and telefax numbers)

Task Force Calcium carbide:

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e-mail zulassung@detia-degesch.de

B.1.1.2 Common name and synonyms

Calcium phosphide.

Calcium carbide (calcium acetylide)

B.1.1.3 Chemical name

IUPAC Calcium phosphide (Tricalcium diphosphide)

Calcium carbide (calcium acetylide)

CA Calcium phosphide

Calcium carbide

B.1.1.4 Manufacturer's development code number

Not available.

B.1.1.5 CAS, EEC and CIPAC numbers

Calcium phosphide

Calcium carbide

CAS: 1305-99-3

CAS: 75-20-7

EC: 215-142-0

EINECS: 200-848-3

B.1.1.6 Molecular and structural formulae, molecular mass

Calcium phosphide

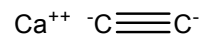
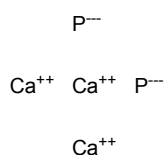
Calcium carbide

Molecular formula: Ca_3P_2

Molecular formula: CaC_2

Structural formula:

Structural formula:



Molecular mass: 182.18 g/mol

Molecular mass: 64.10 g/mol

B.1.1.7 Manufacturer or manufacturers of the active substance

Confidential information, see Volume 4 / Annex C.

B.1.1.8 Method or methods of manufacture

Confidential information, see Volume 4 / Annex C.

B.1.1.9 Specification of purity of the active substance

RMS proposal:

Calcium phosphide 0.08 - 0.52 g/kg

Calcium carbide 765 - 810 g/kg

B.1.1.10 Identity of isomers, impurities and additives

Confidential information, see Volume 4 / Annex C.

B.1.1.11 Analytical profile of batches

Confidential information, see Volume 4 / Annex C.

B.1.2 Identity of the plant protection product

B.1.2.1 Current, former and proposed trade names and development code numbers

Trade name: PRONTOX Wülmausgas

Development code number:

PRONTOX Wülmausgas is the technical product sold unformulated.

B.1.2.2 Manufacturer or manufacturers of the plant protection product

Confidential information, see Volume 4 / Annex C.

B.1.2.3 Type of the preparation and code

Proposed by notifier: Technical product (TK)

Proposed by RMS: Gas generating product (GE)

B.1.2.4 Function

Repellent

B.1.2.5 Composition of the preparation

		[%w/w]
Typical content of the technical active substance	(typ. purity 0.025% calcium phosphide, 80% calcium carbide)	100
Declared (nominal) content of pure active substance	Calcium phosphide	0.025 – 0.05
	Calcium carbide	80

Identity and content of formulants: Confidential information, see Volume 4 / Annex C.

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B.1.3 References relied on

OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

IIA 1.8.1/1	Kampmann, F.W. et al.	1985	Ullmann's Encyclopedia of Industrial Chemistry, 5 th Edition -Calcium Carbide Hoechst AG, Werk Knapsack, Knapsack, nearly Köln, Germany no published	N	authors
IIA 1.10.2/1	anonymous	2005	Specification of technical calcium carbide and Batch-Analysis, Engl. Transl. Of German doc.; ;Spezifikation und Batch-Analysen von technischem Calciumcarbid Degussa AG no Unpublished Confidential	Y	Degussa AG
IIA 1.10.2/2	anonymous	2006	Analysis value of raw carbide; analysis after production, Engl. Transl. Of German doc.: Analysewert Rohkarbide; Analyse nach Produktion Detia no Unpublished Confidential	Y	Detia

WARNING: This document forms part of an EC evaluation data package and should not be used in isolation. Reproduction must not be granted on the basis of this document.

B.2 Physical and chemical properties

B.2.1 Physical and chemical properties of the active substance

The presentation of the dossier was based on calcium carbide as active substance, therefore the calcium phosphide purity is unknown

Table B.2-1 - Summary of the physical and chemical properties of calcium carbide

Study	Method	Material / Purity	Results	Conclusion/Comment	Reference
B.2.1.1 Melting point, freezing point or solidification point	Measurement with micro pyrometer Non GLP	Calcium carbide TK	1845 – 1850 °C The melting point of pure Calcium carbide is around 2160 °C Because of the presence of the main Calcium oxide impurity, the melting point of Calcium carbide is lowered to 1845 °C	No data submitted for Calcium phosphide. Calcium phosphide is an inorganic substance with a melting point of 1600 °C according to International Chemical Safety Cards. For the technical concentrate: Publication submitted in German language.	2.1.1/1 Juza,R., Schuster, H-U. 1961 2.1.1/2 International Chemical Safety Cards: Calcium phosphide ICSC:1126 2002
B.2.1.2 Boiling point			Not relevant as the test material is not a liquid nor a low melting substance	Not required since melting point for calcium phosphide or calcium carbide > 360°C.	
B.2.1.3 Temperature of decomposition or sublimation			Above 2500 °C	No data submitted for calcium phosphide, but not required. For the technical calcium carbide: Publication submitted in German language.	2.1.3/1 Ruff,O., Foerster, E. 1923

Calcium carbide – Annex B.2 – Physical and chemical properties

2007

Study	Method	Material / Purity	Results	Conclusion/Comment	Reference
B.2.1.4 Relative density	EEC A3 pycnometer (air comparison) GLP	Calcium carbide TK	$D_4^{21.5} = 2.30$	No data submitted for calcium phosphide. 2.5 g/cm ³ according to International Chemical Safety Cards. For the technical calcium carbide: Accepted.	2.2/1 Lade, M. 2005 2.1.1/2 International Chemical Safety Cards: Calcium phosphide ICSC:1126 2002
B.2.1.5 Vapour pressure			Statment: Calcium carbide is not volatile at ambient temperatures	No data submitted for calcium phosphide, although we can conclude through the data for other similar compounds, e.g. phosphide compounds, that calcium phosphide has negligible vapour pressure in the dry state. For the technical calcium carbide: Accepted.	2.3.1/01 The Pesticide Manual Thirteenth Edition 2003
B.2.1.6 Volatility, Henry's law constant			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Not applicable for calcium phosphide - reacts with water to produce phosphine. For the technical calcium carbide: Accepted.	

Calcium carbide – Annex B.2 – Physical and chemical properties

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Study	Method	Material / Purity	Results	Conclusion/Comment	Reference
B.2.1.7 Appearance: physical state	Visual assessment	Calcium carbide TK	Solid granules	No data submitted for calcium phosphide. Crystalline powder or lumps according to International Chemical Safety Cards. For the technical calcium carbide: Accepted.	3.7/1 Moser, R. (MSD) 2004 2.1.1/2 International Chemical Safety Cards: Calcium phosphide ICSC:1126 2002
B.2.1.8 Appearance: colour	Visual assessment	Calcium carbide TK	Grey	No data submitted for calcium phosphide. Red-brown and grey according to International Chemical Safety Cards. For the technical calcium carbide: Accepted.	3.7/1 Moser, R. (MSD) 2004 2.1.1/2 International Chemical Safety Cards: Calcium phosphide ICSC:1126 2002
B.2.1.9 Appearance: odour	Organoleptic	Calcium carbide TK	Odour is that of phosphine, garlic like	Accepted.	3.7/1 Moser, R. (MSD) 2004
B.2.1.10 Spectra of the active substance	IR X-ray Non GLP	Calcium carbide TK	IR: wavenumber for CC triple bond (1920 – 2180 cm ⁻¹). X-ray : detection of C ₂ ²⁻ and Ca ²⁺ ions; in the temperature range 25 to 440°C technical calcium carbide posses mainly a tetragonal, flat-centred crystal structure (Phase I)	Publication submitted in German language except for IR characteristics. UV-Vis not applicable NMR not applicable MS not applicable	2.5.1/1 Risser 1997

Calcium carbide – Annex B.2 – Physical and chemical properties

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Study	Method	Material / Purity	Results	Conclusion/Comment	Reference
B.2.1.11 Spectra of relevant impurities				The technical material contains no toxicological and/or ecotoxicological relevant impurities	
B.2.1.12 Solubility in water including effect of pH (4 to 10) on solubility			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Not applicable for calcium phosphide - reacts with water to produce phosphine. For the technical calcium carbide: Accepted.	
B.2.1.13 Solubility in organic solvents			Testing of the technical Calcium carbide is not possible for this property	From the structural formulas of the parts technical calcium carbide is expected to have a very low solubility in organic solvents	
B.2.1.14 Partition coefficient <i>n</i> -octanol/water			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Not applicable for calcium phosphide - reacts with water to produce phosphine. For the technical calcium carbide: Accepted.	
B.2.1.15 Hydrolysis rate			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Not applicable for calcium phosphide - reacts with water to produce phosphine. For the technical calcium carbide: Accepted	

Calcium carbide – Annex B.2 – Physical and chemical properties

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Study	Method	Material / Purity	Results	Conclusion/Comment	Reference
B.2.1.16 Direct phototransformation			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Not applicable for calcium phosphide - reacts with water to produce phosphine, and due to the fact of calcium phosphide be an inorganic salt no absorption at UV range is expected. For the technical calcium carbide: Accepted	
B.2.1.17 Quantum yield			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Not applicable for calcium phosphide - reacts with water to produce phosphine, and due to the fact of calcium phosphide be an inorganic salt no absorption at UV range is expected. For the technical calcium carbide: Accepted	
B.2.1.18 Dissociation constant (pKa)			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Not applicable for calcium phosphide - reacts with water to produce phosphine. For the technical calcium carbide: Accepted	

Calcium carbide – Annex B.2 – Physical and chemical properties

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Study	Method	Material / Purity	Results	Conclusion/Comment	Reference
B.2.1.19 Stability in air, photochemical oxidative degradation			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Calcium phosphide and calcium carbide are stable in the dry state	
B.2.1.20 Flammability	EEC A10 GLP	Calcium carbide TK	Not highly flammable according to EEC A10	For this type of product flammability should be assessed with EEC A12 (contact with water) F: Highly flammable according to European Chemical Substances Information System	2.11.1/01 Lüth, P. 2005 2.11.1/02 European Chemical Substances Information System
B.2.1.21 Auto-flammability	EEC A16 GLP	Calcium carbide TK	390 °C	Accepted.	2.11.2/1 Lade, M. 2005
B.2.1.22 Flash point			Not determined since technical calcium carbide is not a liquid at temperatures < 40 °C.	Accepted.	
B.2.1.23 Explosive properties	EEC A14 GLP	Calcium carbide TK	Thermal sensitivity: not explosive Mechanical sensitivity (shock): not explosive Mechanical sensitivity (friction): not explosive.	Accepted.	2.13/1 Michael-Schulz, H. 2005
B.2.1.24 Surface tension			Testing of the technical Calcium carbide is not possible for this property Technical calcium carbide undergoes decomposition by water as a result of which acetylene, phosphine and Calcium hydroxide are formed.	Accepted.	
B.2.1.25 Oxidising properties			From the structural formulas of the parts of the product it can be concluded that PRONTOX-Wühlmausgas has no oxidising properties	Accepted for technical calcium carbide.	2.15/01 Lüth, P. 2005

B.2.2 Physical, chemical and technical properties of the plant protection products

Table B.2-2 – Product name: PRONTOX Wülmausgas (containing 0.025 – 0.05% of calcium phosphide and 80% of calcium carbide; Gas generating product (GE))

Study	Method	Results	Conclusion/Comment	Reference
B.2.2.1 Appearance: physical state	Visual assessment	Solid granules	Accepted.	IIA 3.7/1 Moser, R. (MSD) 2004
B.2.2.2 Appearance: colour	Visual assessment	Grey	Accepted.	IIA 3.7/1 Moser, R. (MSD) 2004
B.2.2.3 Appearance: odour	Organoleptic	Odour is that phosphine, garlic like	Accepted.	IIA 3.7/1 Moser, R. (MSD) 2004
B.2.2.4 Explosive properties	EEC A14 GLP	Thermal sensitivity: not explosive Mechanical sensitivity (shock): not explosive Mechanical sensitivity (friction): not explosive	Accepted.	IIA 2.13/1 Michael-Schulz, H. 2005
B.2.2.5 Oxidising properties		From the structural formulas of the parts of the product it can be concluded that PRONTOX-Wülmausgas has no oxidising properties	Accepted.	IIA 2.15/01 Lüth, P. 2005
B.2.2.6 Flash point		Not determined since technical calcium carbide is not a liquid at temperatures < 40 °C.	Accepted.	

Calcium carbide – Annex B.2 – Physical and chemical properties

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Study	Method	Results	Conclusion/Comment	Reference
B.2.2.7 Flammability	EEC A10	Not highly flammable according to EEC A10	For this type of product flammability should be assessed with EEC A12 (contact with water) F: Highly flammable according to European Chemical Substances Information System	IIA 2.11.1/01 Lüth, P. 2005 IIA 2.11.1/02 European Chemical Substances Information System
B.2.2.8 Auto-flammability	EEC A16 GLP	390 °C	Accepted.	IIA 2.11.2/1 Lade, M. 2005
B.2.2.9 Acidity/ alkalinity/ pH			Not applicable.	
B.2.2.10 pH (1% in water)			Not applicable.	
B.2.2.11 Viscosity Kinematic Dynamic			Not applicable.	
B.2.2.12 Surface tension			Not applicable.	
B.2.2.13 Relative density	EEC A3 Pycnometer (air comparison) GLP	$D_4^{21.5} = 2.30$		IIA 2.2/1 Lade, M. 2005
B.2.2.14 Bulk or tap density	CIPAC MT186 GLP	Pour density = 1.04 g/ml tap density = 1.11 g/ml		IIIA 2.6.2/1 Walter, D. 2006
B.2.2.15 Stability after storage for 14 days at 54°C		Under dry storage conditions calcium carbide in well ventilated places has a storage stability of at least 5 years. Effects of low and high temperature stability are not known.	Study on accelerated storage stability is required with control analysis of calcium phosphide.	IIA 2.17/1 IIA 2.17/2 Benetka, E. 2005

Calcium carbide – Annex B.2 – Physical and chemical properties

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Study	Method	Results	Conclusion/Comment	Reference
B.2.2.16 Effect of low temperature on stability		Under dry storage conditions calcium carbide in well ventilated places has a storage stability of at least 5 years. Effects of low and high temperature stability are not known.	Not applicable, solid formulation	IIA 2.17/1 IIA 2.17/2 Benetka, E. 2005
B.2.2.17 Shelf life		Under dry storage conditions calcium carbide in well ventilated places has a storage stability of at least 5 years. Effects of low and high temperature stability are not known. Because of calcium carbide is stored in sealed-joint pack with tear-off top and inner packaging there is excluded that water or humid air can penetrate into the steel container. The absolute weight of calcium in the product will not change during storage because volatile compounds within the specified product are not likely to occur Carbon content will change in destructive reactions with humidity only concerning the carbon within the carbide without any effect on the elemental carbon. Acetylene can be determined by gas volumetry. As the amount on acetylene formed is pending on the grain size of the calcium carbide this method seems not appropriate to determine the storage stability. Under normal storage conditions interactions with packaging material are not observed.	According to notifier under dry storage conditions calcium carbide in well ventilated places has a storage stability of at least 5 years. Study on storage stability is required with control analysis of calcium phosphide.	IIA 2.17/1 IIA 2.17/2 Benetka, E. 2005
B.2.2.18 Wettability		Not relevant since no intended for use with water		
B.2.2.19 Persistent foaming		Not relevant since no intended for use with water		
B.2.2.20 Suspensibility		Not relevant since no intended for use with water		
B.2.2.21 Spontaneity of dispersion		Not relevant since no intended for use with water		
B.2.2.22 Dilution stability		Not relevant since no intended for use with water		

Calcium carbide – Annex B.2 – Physical and chemical properties

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Study	Method	Results	Conclusion/Comment	Reference
B.2.2.23 Dry sieve test	CIPAC MT 59 GLP	2000 µm < 99.61% 2000 - 1000 µm: 0.06% 1000 – 500 µm: 0.02% 500 – 355 µm: 0.01% 355 – 250 µm: 0.02% 250 – 150 µm: 0.06% 150 – 75 µm: 0.04% 75 µm > 0.12 % Loss 0.1%	Accepted.	IIIA 2.8.5.1/1 Walter, D. 2006
B.2.2.24 Wet sieve test		Not relevant since no intended for use with water		
B.2.2.25 Size distribution of particles Nominal size range of granules	OECD 110 CIPAC MT 59 CIPAC MT 58.2 GLP	≥ 90% > 2000 µm ≤ 10% > 7100 µm L ₅₀ = 3786 µm	Accepted.	IIIA 2.8.6.1/1 Lade, M. 2005
B.2.2.26 Dust content / particle size	CIPAC MT 171 GLP	Dust = 2.4 mg (0.01%) Since the test item was found nearly dust free a determination of the particle size of dust is not necessary	Accepted	IIIA 2.8.6.3/1 Walter, D. 2006
B.2.2.27 Attrition resistance and friability	CIPAC MT 178 GLP	Attrition resistance = 99.4 %	Accepted.	IIIA 2.8.6.5/1 Walter, D. 2006
B.2.2.28 Emulsifiability, re-emulsifiability and emulsion stability		Not relevant since no intended for use with water		
B.2.2.29 Stability of dilute emulsions		Not relevant since no intended for use with water		
B.2.2.30 Flowability	CIPAC MT 172 GLP	2 weeks at 54°C 84 % (on a 5mm sieve spontaneously) 23.2% (on a 5mm sieve after 20 liftings) 49.8% (on a 7.1mm sieve spontaneously) 0% (on a 7.1mm sieve after 9 liftings) Visual observation showed no caking of the granules	Accepted.	IIIA 2.8.8.1/1 Walter, D. 2006

Calcium carbide – Annex B.2 – Physical and chemical properties

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Study	Method	Results	Conclusion/Comment	Reference
B.2.2.31 Pourability (rinsability)		Not relevant since product is no emulsion or suspension		
B.2.2.32 Dustability		Not relevant since product is not a power		
B.2.2.23 Physical and chemical compatibility of tank mixes		Not relevant since product is ready to use		
B.2.2.34 Adherence and distribution to seeds		Not relevant (product is not intended for seed treatment).		

B.2.3 References relied on

OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

IIA 2.1.1; 2.2; 2.4.1 (2.1.1/2)		2002	International Chemical Safety Cards: calcium phosphide ICSC:1126 Published	N	
IIA 2.2/1	Lade, M.	2005	Relative Density A.3 (OECD 109) Report n° 20050474.02 Siemens AG Prozess-Sicherheit Industriepark Höchst, C 487 D-65926 Frankfurt am Main, Germany yes unpublished	Y	CFW
IIA 2.3.1/1		2002	The Pesticide Manual Thirteenth edition Published	N	
IIA 2.4.1; 2.4.2 (3.7/1)	Moser, R.	2004	Calcium Carbide, Material Safety Data Sheet (according to 91/155/EEC) Version N° 2 Published	N	Skw metallurgie
IIA 2.5.1/1	Risser	1997	Absorption characteristics of the IR spectrum of IR-CaC ₂ a Engl. Transl. of German doc.: Charakteristische Absorption des IR- Spektrums von IR-CaC ₂ a Dr. Weßling Beratende Ingenieure GmbH, Feodor-Lynen-Straße 23, D-30625 Hanover, Germany no unpublished	Y	CFW
IIA 2.11.1/02			European Chemical Substances Information System (ESIS) Published	N	
IIA 2.11.2/1	Lade, M.	2005	Auto flammability (solids- determination of relative self-ignition temperature Report N° - 20050474.03 Siemens AG Prozess-Sicherheit Industriepark Höchst, C 487 D-65926 Frankfurt am Main, Germany yes unpublished	Y	CFW

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OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
IIA 2.13/1	Michael-Schulz, H.	2005	Testing of the substance „ PRONTOX-Wühlmausgas“ according to method EEC A.14 „explosive properties“, annex to Comission Directive 92/69/EEC Federal Institute for Materials Research and Testing Section II. 21”Dangerous Goods/Dangerous Substances; Assessment and Coordination”, Berlin, Germany yes unpublished	Y	CFW
IIA 2.15/1	Lüth, P.	2005	Classification of product „ PRONTOX-Wühlmausgas“ in accordance with method EEC A.17- Oxidising Properties (solids) Federal Institute for Materials Research and Testing Section II. 21”Dangerous Goods/Dangerous Substances;Assessment and Coordination”, Berlin, Germany yes unpublished	Y	CFW

Annex IIIA

IIIA 2.6.2/1	Walter, D.	2006	Pour and tap density of formulation GAB Biotechnologie GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany yes unpublished	Y	CFW
IIIA 2.8.5.1/1	Walter, D.	2006	Dry sieve Analysis of the formulation PRONTOX-Wühlmausgas GAB Biotechnologie GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany yes unpublished	Y	CFW
IIIA 2.8.6.1/1	Lade, M.	2005	Calcium carbide tec. – Particle Size Distribution OECD 110 Siemens AG Prozess-Sicherheit Industriepark Höchst, C 487 D-65926 Frankfurt am Main, Germany yes unpublished	Y	CFW
IIIA 2.8.6.3/1	Walter, D.	2006	Dustiness of the formulation PRONTOX-Wühlmausgas GAB Biotechnologie GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany yes unpublished	Y	CFW

OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
IIIA 2.8.6.5/1	Walter, D.	2006	Friability / Attrition Characteristics of the formulation PRONTOX-Wühlmausgas GAB Biotechnologie GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany yes unpublished	Y	CFW
IIIA 2.8.8.1/1	Walter, D.	2006	Flowability of the formulation PRONTOX-Wühlmausgas GAB Biotechnologie GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany yes unpublished	Y	CFW

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

B.3 Data on application and further information

B.3.1 Data on application relevant to the active substance

B.3.1.1 Function

Repellent.

B.3.1.2 Effects on harmful organisms systemic or not in plants

B.3.1.2.1 Effect

Calcium carbide technical is an effective repellent containing 80 % w/w of calcium carbide and minor quantities (0.025-0.05% w/w) of calcium phosphide. It is applied in granular form for the control of voles (*Arvicola terrestris*) and moles (*Talpa europaea* L.).

It is sold unformulated as the technical active substance, and thus the composition of the formulation and the technical active substance are the same. Calcium carbide is placed in tunnels and burrows of target pests in non-crop situations, away from buildings. In contact with moisture in the soil Calcium carbide breaks down rapidly to produce the gas acetylene, solid calcium hydroxide and minor quantities of the gas phosphine.

The repellent action of technical calcium carbide on harmful organisms (voles and moles) based on the garlic-like odour of phosphine.

B.3.1.2.2 Translocation in plants

Calcium carbide is not translocated in plants apoplastically, symplastically or both.

B.3.1.3 Field of use

Agricultural crops, fruit, vegetable, ornamental growing, grassland, domestic and amateur gardening

B.3.1.4 Harmful organisms controlled and crops or products protected or treated

Existing uses

Germany

Agricultural crops, fruit, vegetable and ornamental growing, grassland, house and allotment areas: *Arvicola terrestris*, *Talpa europaea*;

5-10g PPP/ hole (*Arvicola terrestris*); 4-8g Calcium carbide/ hole.

20g PPP/ hole (*Talpa europaea*); 16g Calcium carbide/ hole.

Application if required.

Calcium carbide – Annex B.3 – Data on application and further information

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Intended uses

Table B.3-1 – Summary of intended uses

(a)	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
Vegetables (NNNWW) Fruit (NNNOO) Ornamental plants (NNNZZ) Agricultural crops (NNNAC) Grassland (NNNFW)	Germany (Northern Europe)	PRONTOX Wühl-mausgas	F	<i>Arvicola terrestris</i> (ARVCTE), <i>Talpa europaea</i> (TALPEU)	GE	800 g/kg Calcium carbide	covered application	all stages	if/ when required	without waiting-time	not applicable	not applicable	4-8g/hole 16g/hole (2-8kg/ha for a maximum infestation level of 500 holes/ha)	not required	

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds

(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).**

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)

(m) PHI - minimum pre-harvest interval

Details of harmful organisms against which protection is afforded

The existing and intended use of Calcium carbide is the protection of agricultural crops, vegetable, fruit and ornamental growing and grassland against damage by voles (*Arvicola terrestris*) and moles (*Talpa europea* L.), respectively.

The voles are widely spread harmful organisms in all types of cultivations and damage plants by eating roots, bulbs and seeds. Little damages of bark attracted the voles and stimulated their gnawing activity. Due to their high fertility, the voles can easily accumulate and cause extensive damage in cultivations.

Effects achieved

The effect on the crop achieved is a protection against damage by eating roots, bulbs and seeds.

B.3.1.5 Mode of action

The action of technical calcium carbide as repellent based on the releasing of phosphine when the impurity calcium phosphide is in contact with the soil humidity.

The garlic-like odour of phosphine is causal for the depopulation in the burrows of voles and moles. The minor concentrations of phosphine in air have not a toxic or other unhealthy effect on the animals.

B.3.1.6 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

There is no information of any occurrence of resistance against calcium carbide in relevant susceptible pests, despite explicit literature searches to obtain any such data.

B.3.2 Data on application relevant to the plant protection product

B.3.2.1 Field of use envisaged e.g. field, protected crops, storage of plant products, home gardening

Agricultural crops, fruit, vegetable, ornamental growing, grassland, domestic and amateur gardening

B.3.2.2 Nature of the effects on harmful organisms

PRONTOX Wühlmausgas is an effective repellent containing 80 % w/w of calcium carbide and minor quantities (0.025-0.05% w/w) of calcium phosphide. It is applied in granular form for the control of voles (*Arvicola terrestris*) and moles (*Talpa europaea* L.).

It is sold unformulated as the technical active substance, and thus the composition of the formulation and the technical active substance are the same. Calcium carbide is placed in tunnels and burrows of target pests in non-crop situations, away from buildings. In contact with moisture in the soil Calcium carbide breaks down rapidly to produce the gas acetylene, solid calcium hydroxide and minor quantities of the gas phosphine.

The repellent action of technical calcium carbide on harmful organisms (voles and moles) based on the garlic-like odour of phosphine.

B.3.2.3 Details of intended use

B.3.2.3.1 Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)

Intended uses

PRONTOX Wühlmausgas is intended for the crops and diseases referred in Table B.3-1, presented in B.3.1.4.

Existing uses

Germany

Agricultural crops, fruit, vegetable and ornamental growing, grassland, house and allotment areas: *Arvicola terrestris*, *Talpa europaea*;

5-10g PPP/ hole (*Arvicola terrestris*); 4-8g Calcium carbide/ hole.

20g PPP/ hole (*Talpa europaea*); 16g Calcium carbide/ hole.

Application if required.

B.3.2.3.2 Details of harmful organisms against which protection is afforded

The existing and intended use of Calcium carbide is the protection of agricultural crops, vegetable, fruit and ornamental growing and grassland against damage by voles (*Arvicola terrestris*), common voles (*Microtus arvalis*) and moles (*Talpa europaea* L.), respectively.

The voles are widely spread harmful organisms in all types of cultivations and damage plants by eating roots, bulbs and seeds. Little damages of bark attracted the voles and stimulated their gnawing activity. Due to their high fertility, the voles can easily accumulate and cause extensive damage in cultivations.

B.3.2.3.3 Effects achieved e.g. sprout suppression

The product has been shown to be effective in preventing damage by rodentia and insectivore to the cultivations.

The effect is repellency of the harmful organisms (voles and moles).

B.3.2.4 Rate of application per unit treated (ha, m², m³, tonne) treated, in terms of g or kg of preparation and active substance

The useful recommended mode of application is at a rate of 5-10g PRONTOX Wühlmausgas/tunnel (*Arvicola terrestris*) and at a rate of 20g PRONTOX Wühlmausgas/burrow (*Talpa europaea* L.).

This corresponds to 4-8g and 16g Calcium carbide/ hole, respectively.

Depending on the context of infestation, this is considered to correspond to a maximum field application rate of 2.5-10kg PPP/ha, i.e. 2-8kg calcium carbide/ha (max. infestation level of 500holes/ ha).

B.3.2.5 Concentration of active substance in material used (e.g. diluted spray, baits, treated seed) in g/l, g/kg, mg/kg or g/tonne

The nominal content of Calcium carbide in PRONTOX Wühlmausgas is 80 % w/w, 800 g/kg, respectively.

PRONTOX Wühlmausgas is used undiluted.

B.3.2.6 Description of the method of application, type of equipment used and type and volume of diluent per unit of area or volume

PRONTOX Wühlmausgas should only be used in conjunction with ancillary tools (e.g. spoon) placed underground. 2-4 days after application, a visual inspection should be take place, and if necessary, a repetition of the application.

PRONTOX Wühlmausgas should never be placed or allowed to remain on the ground surface.

PRONTOX Wühlmausgas decomposes to a small pile of grey powder of Calcium hydroxide which has no adverse effect on the soil, earthworm or plant life.

PRONTOX Wühlmausgas is used undiluted.

B.3.2.7 Number and timing of applications and duration of protection

If required PRONTOX Wühlmausgas may be used at any time of year.

B.3.2.7.1 Maximum number of applications and their timing

A maximum number of applications and their timing is not indicated .

B.3.2.7.2 For each application, growth stages of the crop or plants to be protected

All growth stages of the cultivation may be protected.

B.3.2.7.3 For each application, development stages of the harmful organism concerned

All development stages of voles and moles.

B.3.2.7.4 Duration of protection afforded by each application

The product is intended to be applied once only. If upon inspection of the rodent holes 2-4 days after application, no rodent activity is apparent, then further applications are not necessary, and the duration of protection is principally unrestricted.

B.3.2.7.5 Duration of protection afforded by the maximum number of applications

Please refer to the point 3.2.7.4: full protection is usually afforded by each individual application.

B.3.2.8 Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

A proposal of necessary waiting periods or other precautions to avoid effects on succeeding crops for the product PRONTOX Wühlmausgas is not considered to be required, since uptake in plants is not to be expected.

B.3.2.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

See point 3.2.8

B.3.2.8.2 Limitations on choice of succeeding crops

Limitations on choice of succeeding crops for the product PRONTOX Wühlmausgas is not considered to be required.

B.3.2.8.3 Description of damage to rotational crops

See point 3.2.8

B.3.2.9 Proposed instructions for use as printed, or to be printed, on labels

Copied as in Document C of the dossier:

“The proposed label in German language for Prontox Wühlmausgas, containing 80 % w/w Calcium carbide, and the instructions for use are as follows:

Instructions for use

PRONTOX-vole gas (PRONTOX Wühlmausgas)

Gassing product against voles and moles in meadows, fruit, vegetable, field and ornamental cultivation and in house and allotment areas.

Active substance: 80 % Calcium carbide

Authorisation No. 03365-00

For use as gassing product against voles in meadows and pastures, in fruit, vegetable, field and allotment cultivation 5-10 g (1-2 teaspoons)/burrow to be placed in the opening or hole.

For use as gassing product against moles in fruit, vegetable and allotment agriculture 20 g (4 teaspoons) to be placed in the opening or hole.

The underground passages/burrows are detected with a probing stick and carefully opened in several places. If the burrows are remade after 1-2 hours or partially disturbed with earth, the passages/burrows are occupied. In each passage or hole a few lumps of Prontox vole gas product to be laid out in the passages or holes using a setting tube. The opening to be thereafter immediately closed with a suitable (clump of grass) object (not trodden on), so that the Acetylene gas with low Phosphor- hydrogen admixture produced by soil humidity, will fully penetrate the passages. The resulting gases create an unbearable odour for the animals, so that they promptly leave the affected areas. The residue created after decomposition of the lumps is calcium fertiliser and is therefore harmless for ground and plants.

Bees are not harmed on the basis of the product use described in the authorisation (B3).

The product is not suitable for destruction of vermin. Use is only justifiable when the displaced voles or moles are tolerated on adjoining areas (neighbouring land). Re-infestation is to be expected.

The product is toxic to algae.

The product is toxic to fish and fish food-chain animals.

Product and its residues together with empty containers and packaging are not to come into contact with water.

Use areas

Open land, house and allotment areas (open land)

After infestation can be used throughout the year.

Vegetable, fruit culture, meadows and pastures

The waiting period is determined by the use conditions and/or time of vegetation, between use and benefit (e.g. harvest), the determination of a waiting period in days is therefore not necessary (F).

Ornamental plants

The setting of a waiting period is not relevant (N).

Advice for user protection:

Avoid any unnecessary contact with the product. Misuse can lead to health damage.

Universal protective gloves (plant protection) are to be worn when laying or manipulating the product.

Precautionary measures:

Keep out of the reach of children. Reacts with water with formation of flammable gases.

Irritant to respiratory organs and skin. If swallowed, immediately seek doctor's advice and present packaging or label. Danger of serious eye damage. If contact with eyes, rinse thoroughly with water and consult doctor. If contact with skin, immediately wash off with plenty of water and soap.

Do not breathe dust.

Do not eat, drink or smoke if working. Keep away from food materials, drinks and feed products. Keep container dry.

The use instructions and labelling conditions as per the requirements of section 20 paragraph 2 no. 6, in conjunction with section 15 paragraph 4 of the Plant Protection Law, comply with the conditions of the Federal Institute of Consumer Protection and Food Product Safety.

We accept responsibility for constant quality of the product at the time of delivery but we do not carry any risk arising from use.

Hanover, June 15, 2005"

B.3.2.10 Other/special studies

Other or special studies are not available.

B.3.3 Summary of data on application

The intended use of Calcium carbide is the protection of agricultural crops, vegetable, fruit and ornamental growing and grassland against damage by voles (*Arvicola terrestris*) and moles (*Talpa europea* L.), respectively.

The voles are widely spread harmful organisms in all types of cultivations and damage plants by eating roots, bulbs and seeds. Little damages of bark attracted the voles and stimulated their gnawing activity. Due to their high fertility, the voles can easily accumulate and cause extensive damage in cultivations.

PRONTOX Wühlmausgas is an effective repellent containing 80 % w/w of calcium carbide and minor quantities (0.025-0.05% w/w) of calcium phosphide. It is applied in granular form for the control of voles (*Arvicola terrestris*) and moles (*Talpa europaea* L.). It is sold unformulated as the technical active substance, and thus the composition of the formulation and the technical active substance are the same. Calcium carbide is placed in tunnels and burrows of target pests in non-crop situations, away from buildings. In contact with moisture in the soil calcium carbide breaks down rapidly to produce the gas acetylene, solid calcium hydroxide and minor quantities of the gas phosphine. The repellent action of technical calcium carbide on harmful organisms (voles and moles) based on the garlic-like odour of phosphine.

There is no information of any occurrence of resistance against calcium carbide in relevant susceptible pests, despite explicit literature searches to obtain any such data.

The useful recommended mode of application is at a rate of 5-10g PRONTOX Wühlmausgas/tunnel (*Arvicola terrestris*) and at a rate of 20g PRONTOX Wühlmausgas/ burrow (*Talpa europaea* L.).

The nominal content of Calcium carbide in PRONTOX Wühlmausgas is 80 % w/w, 800 g/kg, respectively, that is used undiluted.

If required PRONTOX Wühlmausgas may be used at any time of year.

A maximum number of applications and their timing is not dictated .

All growth stages of the cultivation may be protected against all development stages of voles and moles.

The product is intended to be applied once only. If upon inspection of the rodent holes 2-4 days after application, no rodent activity is apparent, then further applications are not necessary, and the duration of protection is principally unrestricted.

A proposal of necessary waiting periods or other precautions to avoid effects on succeeding crops for the product PRONTOX Wühlmausgas is not considered to be required, since uptake in plants is not to be expected.

Limitations on choice of succeeding crops for the product PRONTOX Wühlmausgas is not considered to be required.

B.3.4 Further information on the active substance

Calcium phosphide

No specific information was submitted for calcium phosphide.

B.3.4.1 Recommended methods and precautions concerning handling, storage, transport or fire

A Material Safety Data Sheet for the technical calcium carbide was provided.

Safe handling:

Avoid contact with skin, eyes and clothing.

Provide appropriate exhaust ventilation at places where dust is formed.

Open and handle receptacle with care.

The usual precautionary measures are to be adhered to when handling chemicals.

Storage:

Keep containers tightly closed in a dry, cool and well-ventilated place.

Keep in a well-ventilated place.

Cover with dry inert gas.

Suitable material for receptacles and pipes: steel or stainless steel.

Incompatible with acids and bases.

Incompatible with oxidising agents.

Never allow product to get in contact with water during storage.

Transport:



Highly flammable



Irritant

Land transport ADR/RID

ADR/RID classe: 4.3(W2) Substance which, in contact with water, emit flammable gases.

Danger code (Kemler): 423

UN-Number: 1402

Packaging group: II

Hazard label: 4.3

Description of goods: 1402 CALCIUM CARBIDE

Maritime transport IMDG

IMDG class: 4.3

UN-Number: 1402

Label: 4.3

Packaging group: II

EMS Number: F-G,S-N

Marine pollutant: No

Air transport ICAO-TI and IATA-DGR

ICAO/IATA class: 4.3

UN-Number: 1402

Label: 4.3

Packaging group: II

Proper shipping name: CALCIUM CARBIDE

Fire:

Suitable extinguishing agents

Dry sand

Dry chemicals

For safety reasons unsuitable extinguishing agents

Foam

Water

Special hazards caused by the substance, its products of combustion or resulting gases

In case of fire, the following hazardous smoke fumes may be produced

Carbon oxides.

Protective equipment

In case of fire, wear respiratory protective equipment independent of surrounding air and chemical protective suit.

B.3.4.2 Procedures for destruction or decontamination

B.3.4.2.1 Controlled incineration

Calcium carbide is at 800 °C a stable compound. In principle, above 2500 °C complete decomposition takes place.

B.3.4.2.2 Others

Unused Calcium carbide material or other such waste and contaminated materials should be disposed of as specified by existing local, state and federal regulations concernin hazardous waste disposal. In accordance with regulations for special waste, must be taken after pre-treatment, to an authorised special waste disposal site.

B.3.4.3 Emergency measures in case of an accident

Personal precautions:

Inhalation:

Supply fresh air; consult doctor in case of complaints.

Oxygen or artificial respiration is needed.

Skin contact:

Take off contaminated clothing and shoes immediately.

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

Eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Ingestion:

Call for a doctor immediately.

Rinse out mouth and then drink plenty of water

Do not induce vomiting.

Information for doctor:

Symptoms:

Nausea.

Vomiting.

Irritation of skin and mucous membranes.

In contact with aqueous liquids, the product hydrolyses to flammable gases and strong alkaline hydroxide.

Environmental precautions:

Sweep up and shovel.

Avoid formation of dust.

Keep away from water.

Methods for cleaning up

Collect mechanically

Avoid dust formation

Protect from water and humidity

Place in suitable containers for recycling or waste management.

B.3.5 Further information on the plant protection product

B.3.5.1 Packaging (Type, material, size, etc) compatibility of the preparation with proposed packaging materials

B.3.5.1.1 Description of the packaging

Report: IIIA 4.1.1

Köhler, U., Description and specification of the packaging, June, 2004

- 1) 250 g tear-off top pack, size 73/88 mm, steel full tear-off top, gold painted inside and outside, opened, base smooth and exterior painted gold, release supplied, pack polished inside, however seam covered, body painted white outside and dual colour printed, black, orange.
- 2) 500 g sealed-joint pack, body of polished tinsplate, steel tear-off top, gold painted both sides, exterior painted white, orange-black printed, HKS 6, RAL 9005.

B.3.5.1.2 Suitability

Report: IIIA 4.1.2

Wienecke, B.-U., Taegner, W., Gesetz über die Beförderung gefährlicher Güter-Überwachung der Serienfertigung von Gefahrgutverpackungen – Zulassungsschein Nr. D/BAM 5330/1A2W und D/BAM 5331/1A2W ”, March 09, 1998

Information submitted in German language.

Authorisation certificate No. D/BAM 5330/1A2W and D/BAM5331/1A2W of 9 March 1998

B.3.5.1.3 Resistance to its contents

In accordance with the report by BAM (see above) it is concluded that the packaging material is suitable for packaging and transport of PRONTOX Wühlmausgas.

B.3.5.2 Procedures for cleaning application equipment

The submission of information on procedures for cleaning application equipment for the product PRONTOX Wühlmausgas is not considered to be required, since PRONTOX is placed directly into the holes of voles with the aid of an ancillary tool (e.g. drop tube, drop gun), without the use of any further equipment which may become contaminated

B.3.5.3 Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment

B.3.5.4 Recommended methods and precautions concerning: handling, storage, transport or fire

Handling:

Carefully open and handle containers.

Avoid dust formation and dust deposition.

Handle only in well ventilated areas

Wear respiratory protection during transfer of larger quantities without exhaust ventilation.

Restrict amount stored in the workplace.

Storage:

Store containers tightly closed in a dry, cool and well-ventilated place.

Use steel containers.

Respect IVA guideline “fire prevention in plant protection product stores”

Recommended storage temperature: -5°C to +30°C.

Respect TRGS 515 (“Storage of inflammable substances”)

VCI storage class: 4.3

Do not store with acids, lyes and oxidative products

Do not store with food materials

Keep away from water

Keep out of children.

Transport:

Land transport ADR/RID

ADR/RID classe: 4.3
Classification code: W2
Packaging code: II
Limited quantities (3.4.6): LQ11
Carriage conditions (1.1.3.6): 2
UN-Number: 1402
Packaging group: II
Description of goods: 1402 CALCIUM CARBIDE

Maritime transport IMDG

IMDG class: 4.3
UN-Number: 1402
MFAG: 705
EMS Number: F-G,S-N
Proper shipping name: CALCIUM CARBIDE

Air transport ICAO-TI and IATA-DGR

ICAO/IATA class: 4.3
UN-Number: 1402
Packaging group: II
Proper shipping name: CALCIUM CARBIDE

B.3.5.5 Emergency measures in case of an accident

Precautionary measures for affected persons:

Arrange sufficient ventilation
Avoid dust formation
Wear personal protective clothing
Keep ignition sources away
Wear respiratory protection if dust effect

Environmental protective measures:

Do not allow to reach sewers/surface water/ground water.

Procedures for cleaning and collection

Collect mechanically
Avoid dust formation
Protect from water and humidity
Place in suitable containers for recycling or waste management.

B.3.5.6 Procedures for destruction or decontamination

B.3.5.6.1 Possibility of neutralisation

Small quantities

Dry granules and dust must be swept and picked up carefully without raising dust, filled into suitable containers and closed up tightly.

With water PRONTOX Wühlmausgas rapidly liberating the highly flammable gas Acetylene and the basic compound Calcium hydroxide. The most of the Acetylene is escaping from water in the air.

The contaminated water show an alkaline reaction (pH : ≈ 10).

The first step in decontamination is the neutralisation with diluted acid, e.g. diluted hydrochloric acid to calcium chloride. The products of neutralisation are aqueous salt solutions. The neutralized waste should be disposed of as specified by existing local, state and federal regulations concerning hazardous waste disposal.

Large quantities

The proposed procedures are comparable with above. Additional ventilation is necessary to prevent the generation of an explosive Acetylene/air mixture.

B.3.5.6.2 Controlled incineration

Calcium carbide is at 800 °C a stable compound. In principle, above 2500 °C complete decomposition takes place.

B.3.5.6.3 Others

Other methods are not available.

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

B.3.6 References relied on

OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

IIA 3.7/1	Moser, R.	2004	Calcium Carbide, Material Safety Data Sheet (according to 91/155/EEC) Version No. 2 Published	N	Skw metallurgie
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Annex IIIA

IIIA 4.1.1/1	Köhler, U.	2004	Description and specification of the packaging Chemische Fabrik Wülfel, Hanover, Germany no unpublished	Y	CFW
IIIA 4.1.2/1	Wienecke, B.-U., Taegner, W.	1998	Gesetz über die Beförderung gefährlicher Güter- Überwachung der Serienfertigung von Gefahrgutverpackungen – Zulassungsschem Nr. D/BAM 5330/1A2W und D/BAM 5331/1A2W Bundesanstalt für Materialforschung und – prüfung D-12200 Berlin, Germany no unpublished	Y	CFW

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B.4 Proposals for classification and labelling

B.4.1 Proposals for the classification and labelling of the active substance

Calcium phosphide based on European Chemical Bureau – European Chemical Substances Information System (ECB-ESIS) is classified as follows:

Hazard symbols:	F	Highly flammable
	T+	Very toxic
	N	Dangerous for the environment
Indication of danger:		F: Highly flammable
		T+: Very toxic
		N: Dangerous for the environment
Risk phrases:	R15/29	Contact with water liberates toxic, extremely flammable gas
	R28	Very toxic if swallowed
	R50	Very toxic to aquatic organisms
Safety phrases:	S1/2	Keep locked up and out of the reach of children
	S22	Do not breathe dust
	S43	In case of fire, use... (indicate in the space the precise type of fire-fighting equipment. If water increases risk, add – “Never use water”)
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets)

Calcium carbide is classified in Annex I of Council Directive 67/548/EEC (19th ATP) as **F** (highly flammable), **R15, S8, S43** (Calcium carbide liberates acetylene in contact with water in hazardous quantities. Acetylene is an extremely flammable gas).

The manufacturer proposes to additionally classify the a.s. as **Xi** (irritant); risk phrases **R37/38** (irritating to respiratory system and skin), and **R41** (risk of serious damage to eyes).

However, RMS proposes to classify calcium carbide as **C (corrosive), R35 (causes severe burns)** due to its high pH in contact with water (see point B.6.2.4), and as demonstrated by the several acute toxicity studies that were not performed considering this property of the a.s. (see point B.6.2.1 to B.6.2.6). The proposal is also based on human experience (see medical data, point B.6.9.1 and B.6.9.4) where it is shown that, although dry calcium carbide in contact with skin may cause “only” dermatitis, contact with moist skin -and mucous membranes- leads to ulceration and scarring or full thickness burns. **R37 (irritating to respiratory system)** is based on human data (see medical data, point B.6.9.1, B.6.9.2 and B.6.9.4).

RMS proposal:

Hazard symbols:	F	Highly flammable
	C	Corrosive
	N	Dangerous for the environment
Risk phrases:	R15	Contact with water liberates extremely flammable gases.
	R35	Causes severe burns.
	R37	Irritating to respiratory system.
	R51/53	Toxic to Aquatic organisms. May cause long term adverse effects in the aquatic environment.
Safety phrases:	S1/2	Keep locked up and out of the reach of children
	S8	Keep container dry.
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
	S43	In case of fire, use sand. Never use water.
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
	S60	This material and its container must be disposed of as hazardous waste.
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets)

B.4.2 Proposals for the classification and labelling of preparations

As the preparation is the same as the technical active substance, the proposal for its classification is the same as referred above.

WARNING: This document forms part of an EC evaluation data package and should not be used in isolation. Registration must not be granted on the basis of this document.

B.4.3 References relied on

OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

IIA 2.11.1/02			European Chemical Substances Information System (ESIS) Published	N	
IIA 5.2.1/1	Wolf, T.	2006	Calcium Carbide: Acute Oral Toxicity Study with Rats (Acute Toxic Class Method), ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria. Report No. ARC-L-1913, GLP unpublished	Y	CFW
IIA 5.2.1/2	Hinkamp, D.L.	1998	Alkaline materials, Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4 th edition, Volume 4, Part XVIII, 104 Guide to Chemicals, Table 104.18. Not GLP published	N	author
IIA 5.2.1/3	Gangolli, S.	1999	The Dictionary of Substances and their Effects, 2 nd ed. Royal Society of Chemistry, UK vol. 2 Not GLP published	N	Authors
IIA 5.2.1/4	Deichmann, W.B., Gerarde, H.W.	1969	Toxicology of Drugs and Chemicals, Academic Press New York and London, p. 353 Not GLP published	N	authors
IIA 5.2.2/1	Bernat, E.	2006	Calcium Carbide: Acute Dermal Toxicity Study with Rats, ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria. Report No. ARC-L-1931 GLP unpublished	Y	CFW
IIA 5.2.2/2	Hinkamp, D.L.	1998	Alkaline materials, Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4 th edition, Volume 4, Part XVIII, 104 Guide to Chemicals, Table 104.18. Not GLP published	N	author
IIA 5.2.2/3	Gosselin, R.E. <i>et al.</i>	1984	Clinical Toxicology of Commercial Products, 5 th edition Baltimore, Williams and Wilkins, p. II-103-105 Not GLP published	N	authors

OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
IIA 5.2.3/1	Hinkamp, D.L.	1998	Alkaline materials, Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4 th edition, Volume 4, Part XVIII, 104 Guide to Chemicals, Table 104.18. Not GLP published	N	author
IIA 5.2.3/2	ACGIH	1991	Calcium oxide: Documentation of the threshold limit values and biological exposure indices, 6 th edition Cincinnati, OH, American Conference of Governmental Industrial Hygienists, pp. 200-201. Not GLP published	N	ACGIH
IIA 5.2.3/3	Richardson, M.L., Gangolli, S.	1993	The Dictionary of Substances and their Effects, Royal Society of Chemistry, UK, vol. 2 Not GLP published	N	authors
IIA 5.2.4/1	Wolf, T.	2006	Calcium Carbide: Acute Dermal Irritation/Corrosion Study with Rabbits, ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria. Report No. ARC-L-1914 GLP unpublished	Y	CFW
IIA 5.2.4/2	Hinkamp, D.L.	1998	Alkaline materials, Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4 th edition, Volume 4, Part XVIII, 104 Guide to Chemicals, Table 104.18. Not GLP published	N	author
IIA 5.2.4/3	Gosselin, R.E. <i>et al.</i>	1984	Clinical Toxicology of Commercial Products, 5 th edition Baltimore, Williams and Wilkins, p. II-103-105 Not GLP published	N	authors
IIA 5.2.5/1	Wolf, T.	2006	Calcium Carbide: Acute Eye Irritation/Corrosion Study with Rabbits, ARC Seibersdorf research GmbH, A-2444 Seibersdorf, Austria. Report No. ARC-L-1915 GLP unpublished	Y	CFW
IIA 5.2.5/2	Hinkamp, D.L.	1998	Alkaline materials, Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4 th edition, Volume 4, Part XVIII, 104 Guide to Chemicals, Table 104.18. Not GLP published	N	author

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IIA 5.2.5/3	Grant, W.M.	1986	Toxicology of the Eye - Effects on the Eyes and Visual System from Chemicals, Drugs, Metals and Minerals, Plants, Toxins and Venoms; Charles C. Thomas Publisher, Springfield, IL, 3 rd edition, p. 166 Not GLP published	N	author
IIA 5.2.5/4	Gosselin, R.E. <i>et al.</i>	1984	Clinical Toxicology of Commercial Products, 5 th edition Baltimore, Williams and Wilkins, p. II-103-105 Not GLP published	N	authors
IIA 5.2.6/1	Sattler, K.	2006	Calcium Carbide: Skin Sensitisation Study (Guinea Pig Maximisation Test), ARC Seibersdorf research GmbH, A.2444 Seibersdorf, Austria. Report No. ARC-L-1891, GLP unpublished	Y	CFW
IIA 5.2.7/1	Stecher, P.G. <i>et al.</i>	1968	The Merck Index, An Encyclopedia of Chemicals and Drugs, 8 th ed., Merck & Co., Inc., Rahway, N.J., USA Not GLP published	N	
IIA 5.8.1/1	Richardson, M.L., Gangolli, S.	1993	The Dictionary of Substances and their Effects, Royal Society of Chemistry, UK, vol. 2 Not GLP published	N	authors
IIA 5.8.1/3	Stecher, P.G. <i>et al.</i>	1968	The Merck Index, An Encyclopedia of Chemicals and Drugs, 8 th ed., Merck & Co., Inc., Rahway, N.J., USA Not GLP published	N	
IIA 5.8.2/1	Gangolli, S.	1999	The Dictionary of Substances and their Effects, 2 nd ed. Royal Society of Chemistry, UK vol. 2 Not GLP published	N	Authors
IIA 5.8.2/2	Gosselin, R.E. <i>et al.</i>	1984	Clinical Toxicology of Commercial Products, 5 th edition Baltimore, Williams and Wilkins, p. II-103-105 Not GLP published	N	authors
IIA 5.8.2/3	Stecher, P.G. <i>et al.</i>	1968	The Merck Index, An Encyclopedia of Chemicals and Drugs, 8 th ed., Merck & Co., Inc., Rahway, N.J., USA Not GLP published	N	

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IIA 5.8.3/1	Hinkamp, D.L.	1998	Alkaline materials, Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4 th edition, Volume 4, Part XVIII, 104 Guide to Chemicals, Table 104.18. Not GLP published	N	author
IIA 5.8.3/2	Richardson, M.L., Gangolli, S.	1993	The Dictionary of Substances and their Effects, Royal Society of Chemistry, UK, vol. 2 Not GLP published	N	authors
IIA 5.8.5/1	Hinkamp, D.L.	1998	Alkaline materials, Encyclopaedia of Occupational Health and Safety, International Labour Office, Geneva, Switzerland, 4 th edition, Volume 4, Part XVIII, 104 Guide to Chemicals, Table 104.18. Not GLP published	N	author
IIA 5.8.5/2	Gosselin, R.E. <i>et al.</i>	1984	Clinical Toxicology of Commercial Products, 5 th edition Baltimore, Williams and Wilkins, p. II-103-105 Not GLP published	N	authors
IIA 5.9.1/1	Ergenzinger, M.	2005	Calcium carbide – occupational medical statement, Degussa AG, Department of occupational medicine, SKW Trostberg, Germany Not GLP unpublished	Y	SKW Trostberg
IIA 5.9.1/2	NIOSH/OSHA	1981	Occupational Health Guidelines for Chemical Hazards, Occupational Health Guideline for Calcium Oxide, U.S. Department of Health and Human Services and U.S. Department of Labor, pp 208-211 Not GLP published	N	NIOSH/O SHA
IIA 5.9.2/1	Begemann, K.	2005	Summaries of three cases of health impairment relating to Calcium carbide Federal Institute for Risk Assessment (BfR), Technical group 32: poisoning and product documentation, Poisons Assessment Centre, Berlin, Germany Not GLP unpublished	N	BfR
IIA 5.9.4/1	Bronstein, A.C., Currance, P.L.	1988	Emergency Care for Hazardous Materials Exposure, 2 nd edition St. Louis, Mo. Mosby Lifeline Not GLP published	N	authors

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IIA 5.9.6/1	Bronstein, A.C., Currance, P.L.	1988	Emergency Care for Hazardous Materials Exposure, 2 nd edition St. Louis, Mo. Mosby Lifeline Not GLP published	N	authors
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Annex IIIA

IIIA 7.3.2	Köhler, U.	2005	PRONTOX Wühlmausgas, Instructions for use, Chemische Fabrik Wülfel GmbH & Co. KG, Hannover, Germany Not GLP published	N	CFW
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B.5 Methods of analysis

B.5.1 Analytical methods for technical active substance and formulation analysis

B.5.1.1 Methods for the analysis of pure active substance in the active substance as manufactured

Calcium phosphide (Phosphine)

References: IIA 1.10.2/1

Specification and Batch Analyses of Calcium Carbide, May 23, 2005

Principle of the method:

Phosphine is determined by gas-chromatography.

Findings:

Table B.5-1 – Validation data for the determination of phosphine in the technical concentrate material

Impurity	Specificity / interferences	Linearity (R ²) (conc. range)	Accuracy (n=5)		Repeatability (%RSD)
			Fortification level	Mean recovery (%)	
Phosphine	Not submitted	Not submitted	Not submitted	Not submitted	Not submitted

The specificity of the method was not submitted.

Conclusion:

Insufficient data was provided to allow the acceptability of this method.

Full description of the method for the determination of phosphine and correspondent validation were not submitted.

CIPAC method:

No existing CIPAC method was found to be applicable for analysis of phosphine in the technical material.

Calcium carbide

References: IIA 1.9.3/1

DIN 53 922, Calciumcarbid, Deutsches Institut für Normung e.V., July, 1979

IIA 1.10.2/1

Specification and Batch Analyses of Calcium Carbide, May 23, 2005

Principle of the method:

The determination of the calcium carbide and free calcium oxide content is performed in two steps:

First step – determination of total amount of calcium in form of CaO by AES-ICP (atom emission spectroscopy- inductively coupled plasma) method. Aqua regia decomposition (AR) DIN EN 13657, ICP measurement.

Second step – determination of acetylene, released from product, on the basis of guideline DIN 53 992, Calciumcarbid, Deutsches Institut für Normung e.V., July, 1979. The gas yield of the carbide is to be determined by gasification, in excess of water previously saturated with acetylene.

Calculation of CaC_2 and free CaO content.

Findings:

Table B.5-2 – Validation data for the determination of calcium carbide and free calcium oxide in the technical material

	Linearity (linear between), Corr. Coeff.	Precision – repeatability (%RSD)	Interference
AES-ICP	Not submitted	Not submitted	Not submitted
DIN 53 992	Not required. International accepted method.		

Conclusion:

Insufficient data was provided to allow the acceptability of the method for determination of calcium carbide and free calcium oxide in the technical concentrate material

Full description of the method for the determination of total amount of calcium and correspondent validation were not submitted.

B.5.1.2 Methods for the determination of significant and/or relevant impurities and additives (e.g. stabiliser) in the active substance as manufactured

Confidential information, see Volume 4 / Annex C.

B.5.1.3 Analytical methods for the determination of the active substance in plant protection products

PRONTOX Wülmausgas is the technical product sold unformulated.

B.5.1.4 Analytical methods for determination of relevant impurities and formulants in plant protection products

PRONTOX Wülmausgas is the technical product sold unformulated.

B.5.2 Analytical methods (residue) for plants, plant products, foodstuffs (of plant and animal origin), feedingstuffs

Relevant residues of calcium phosphide or calcium carbide in food of plant and animal origin are not expected to occur. The setting of MRL is not necessary and therefore not defined. Therefore residue analytical methods for these matrices are not required.

B.5.3. Analytical methods (residues) for soil, water, air

Relevant residues of calcium phosphide or calcium carbide in the environmental compartments are not expected to occur. Therefore residue analytical methods in soil, water and air are not required.

B.5.4 Analytical methods (residue) in body fluids and tissues

Methods for the determination of residues in body fluids and tissues are not required since relevant residues of calcium phosphide or calcium carbide are not expected to occur.

B.5.5 Evaluation and assessment

B.5.5.1 Analytical methods for technical active substance and formulation analysis

Unsufficient data was provided to allow the acceptability of the methods for determination of calcium phosphide, calcium carbide and impurities in the technical calcium carbide.

Full description of the methods and correspondent validation data were not submitted. Notifier stands that section 2 is not required according to requirements for substances listed in Part A of the Commission Regulation guidance document (Sanco/10393/2004-rev.4 08/10/04).

PRONTOX Wülmausgas is the technical product sold unformulated.

B.5.5.2 Analytical methods for residues analysis

Relevant residues of calcium phosphide or calcium carbide in food of plant and animal origin and in the environmental compartments are not expected to occur. No residue definition is proposed; therefore analytical methods for residues analysis are not required.

Methods for the determination of residues in body fluids and tissues are not required since relevant residues of calcium phosphide or calcium carbide are not expected to occur due to their degradation to phosphine and acetylene respectively.

B.5.6 References relied on

OECD data point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection claimed Y/N	Owner
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Annex IIA

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Annex IIIA

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